



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: James W. Holley, Jr.

Assignee: Insta-mix Inc. Subsidiary A (DBA Umix, Inc.)

Title: FLOW CONTROL ELEMENT INCLUDING ELASTIC MEMBRANE
WITH PINHOLES

Serial No. 10/758,573 File Date: January 13, 2004

Examiner: S. Weaver Art Unit: 3727

Docket No.: UMX-011-1P US

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF BENGT LAGER UNDER 37 CFR 1.132

I, the undersigned named inventor, declare as follows.

1. This declaration accompanies a Response to Third Office Action, which is responsive to the Office Action Mailed on 12/14/04.

2. I started Regal Lager, Inc. together with my wife Luanne Whiting-Lager in 1991. I am currently the President of Regal Lager, and manage the sales and the relationships with Regal Lager's different vendors. I, together with Luanne, decide what products will be represented by Regal Lager.

3. For the first 10 years Regal Lager represented only Baby Björn. In 2001 Baby Björn was put up for sale by the owner, and at that point Regal Lager started looking around for

other products to represent. In the indicated years Regal Lager initiated representation of the following product lines:

- 2001 Diaper Dekor
- 2001 AeroSleep
- 2001 Amtoys/Noukie's
- 2002 Lascal
- 2003 Second Nature (Umix) + Anna Cecilia

4. Regal Lager has received numerous awards over the years for its products and services:

- 1995 Product of the Year from NINFRA (Biggest buying group of independent stores)
- 1996 Manufacturer of the Year IFRA (The organization for sales reps in our industry)
- 1997 Product of the Year from BFP (Second biggest buying group)
- 1998 American Baby Best of the Year Award
- 2000 Swedish Trade Council The Annual Achievement Award for promoting Swedish Business in North America
- 2001 American Baby Best of the Year Award
- 2002 American Baby Best of the Year Award

5. I have been involved with Juvenile Products Manufacturers Association, Inc. (JPMA) since 1996 and been on its board since 2001. For the last 1½ year I have served as the chairman of the association.

6. As President of Regal Lager I have been responsible for looking for and negotiating with potential new suppliers.

7. I met James Holley (Jim) for the first time at the annual meeting for JPMA in 1998.

8. At the annual JPMA Trade Show in Dallas in May 2003, where Regal Lager already had five lines of products and definitely were not actively looking for any more lines, my wife and I were introduced to the unique spill proof nipple Jim had developed (later to be named the Second Nature nipple). The first reaction was that we already have a full plate and the bottle/feeding market is an unbelievably tough and competitive market with some really big and dominant players that we really don't want to get involved with.

However, this new technology with a membrane and pinholes making the bottle spill proof was very fascinating, and after discussing things more we truly realized how different and unique this was. Jim described his vision for the line and that he was looking for a partner to do the sales and marketing. The more we discussed and researched the market, the more we realized how much better this nipple was by basically mimicking a mother's breast with multiple pores. No other nipple out there had the combination of spill proof, flexible flow and multiple pores.

This simply turned out to be way more interesting than we could have ever imagined when we saw the product the first time and it became very obvious to us that this was something we definitely wanted to be involved with. Luckily enough Jim believed we could help with the sales and marketing and with a great personal chemistry we were able to reach an agreement to work together on this project.

9. As is visible from our packaging and advertising, the spill proof function of the nipple is something we are pushing very hard and it's basically the most important feature for two reasons.

The first benefit is quite obvious that the bottle doesn't leak when dropped or left laying in a bed, sofa, carpet or car and thereby avoiding stains.

The second benefit of the spill proof function is possibly greater and not as obvious initially. Normal bottles with one or multiple holes in the nipple allow the milk to drip/flow out of the nipple without any effort on the part of the baby. In most instances it flow so fast that the baby can't keep up with and swallow fast enough, resulting in almost choking the baby and milk pouring out of the side of the mouth of the baby. Not only is this a waste of precious milk, it also makes the baby's clothes wet. The ease of getting milk "spoils" the baby and they basically become "lazy" and will not go back to mom's breast where they have to suckle quite hard in order to get milk. This creates "nipple confusion" and premature ending to the breastfeeding process for many mothers. This is exactly why the whole breastfeeding/lactation community is so against the use of bottles. With the Second Nature nipple no milk comes out unless the baby suckles on the nipple. This means the baby has to work the same way as getting it from the breast and it also prevents wasting milk leaking out of the baby's mouth.

When demonstrating and selling Second Nature bottles, the spill proof functionality provided by the Second Nature nipple is the feature that catches everybody's attention, especially buyers as they have never seen anything like it. It doesn't matter how seasoned a buyer is, when you turn the bottle upside down and shake it and nothing leaks it truly catches their attention.

The same goes for people in the medical field. We have received lots of phone calls from medical professionals that have been intrigued by the information about spill proof in our advertising. Feedback from medical practitioners is listed in

the Declaration of Jeff Durkee, which is submitted with the Response.

In addition to feedback from the medical community, additional feedback from retailers and other third party sources that has been received by Regal Lager regarding the Second Nature Nipple is listed in the Declaration of Jeff Durkee, Regal Lager's Director of Sales, which is submitted with the Response.

Without the spill proof function of the Second Nature nipple, I believe the Second Nature nipple/bottle would be just another me too product, and it would have been impossible to have achieved the placement and sales that we have achieved to date.

10. Appended to this declaration as Appendix A are overall sales data for products incorporating Second Nature Nipples for the last six months. These sales numbers are currently relatively small due to the current policy of selling these products through specialty retailers, which is a common method for introducing new products. However, we are currently negotiating the addition of new retailers in 2005 that should significantly increase the sales numbers.

11. I declare that all statements made herein of my own respective knowledge are true, all statements made herein on information and belief are believed to be true, and all statements made herein are made with the knowledge that whoever, in any matter within the jurisdiction of the Patent and Trademark Office, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent

statement or entry, shall be subject to the penalties including fine or imprisonment or both as set forth under 18 U.S.C. 1001, and that violations of this paragraph may jeopardize the validity of the application or this document, or the validity or enforceability of any patent resulting therefrom.

Date: 4-11-05

Bengt Lager
Bengt Lager



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Date: March 14, 2005

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DECLARATION OF JEFF DURKEE UNDER 37 CFR 1.132

I, the undersigned named inventor, declare as follows.

1. This declaration accompanies a Response to Third Office Action, which is responsive to the Office Action Mailed on 12/14/04.

2. My college training is in medicine. I have a Bachelors Degree from the University of Massachusetts. After college, I worked for a two different private Ambulance Services based in Massachusetts, including a position for one as General Manager.

3. I moved to New Hampshire to further my education in emergency medicine as a Paramedic. I studied at one of the only

colleges in the U.S. offering a degree program in Paramedics where I maintained a 4.0 gpa.

4. I have been in the Juvenile Products industry since July of 1987. I started working for a company as an Independent Sales Rep, handling primarily Juvenile Specialty Stores, and Catalog Showrooms.

5. Over the years I increased my account responsibility handling major customers such as Ames, Bradlees, Caldor, Lechmere, Hills, Kay Bee Toys, and others.

6. I started in the industry representing Century Products, one of the largest Juvenile Product manufacturers in the industry at the time. I was with Century for 10 years until they were purchased by Graco.

7. In 1997, I took over the company I was working with, becoming the president and CEO.

8. In the fall of 2000, I decided to change direction and work as a Sales Manager of a start up company in the U.S., Stokke - a Scandinavian furniture manufacturer. After two years I assumed my current position of Director of Sales for Regal Lager, overseeing sales for six manufacturers, and two sales forces with over 65 "road reps."

9. Over the years I have represented a variety of companies with various product offerings. One of those companies was Avent, a leading manufacturer of feeding products in our industry. I was with Avent for over two years.

10. During my time with Avent I became fully skilled in selling their products, from the basis of a complete understanding of the benefits to the child and the parent that Avent products offered.

11. With Avent, I was able to draw upon my medical background and understanding of Endocrinology and the roles that various hormones play in the breastfeeding process, and, the anatomy and physiology of the oral cavity as it relates to the design of artificial nipples.

12. When I first saw the Second Nature nipple, I immediately knew this was a revolutionary product in feeding. The design emulates the function of the human nipple, and I knew there was nothing out there like it, and that the medical community would immediately recognize the uniqueness and advantages of this nipple design.

13. Our initial response has been overwhelmingly positive. As anticipated, we are receiving calls every week from Lactation Consultants (LC's), Child Birth Educators (CBE's), Neonatal Intensive Care Nurses, Speech Pathologists focusing on children with problem swallowing, Pediatricians, and others in the medical field.

14. We are sending out samples to these medical professionals for their use and review, and the feedback has all been positive.

15. Medical professionals are echoing the same message, "This is the first feeding system we as a lactation community

can get behind and endorse." There is nothing on the market like the Second Nature nipple.

16. The Second Nature Nipple has been presented by one of the RN members of the Rhode Island Breastfeeding Coalition, at one of their meetings. Another RN is presenting at another upcoming meeting of the RI Breastfeeding Coalition.

17. The bottles are currently being tested by two of the largest and most prominent medical facilities in the country, The Children's Hospital of Philadelphia and the Riley Children's Hospital in Indianapolis.

18. Many retailers have told us that they are dropping or reducing their selection of Avent products to make room for Second Nature, which they feel is truly revolutionary and the first new innovation in feeding in years.

19. One of our major retailers in Mississippi has been indicating to us that his sales of Second Nature surpassed his Avent sales and have continued to do so.

20. Baby Center - one of our largest on-line retailers, has seen a rapid increase in sales since we started shipping the Second Nature system, increasing their orders from 48, to 144, to 500 pieces per order. Appended to this declaration as Appendix 1 are exemplary listing of comments received on the Babycenter.com website.

21. I declare that all statements made herein of my own respective knowledge are true, all statements made herein on information and belief are believed to be true, and all

statements made herein are made with the knowledge that whoever, in any matter within the jurisdiction of the Patent and Trademark Office, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be subject to the penalties including fine or imprisonment or both as set forth under 18 U.S.C. 1001, and that violations of this paragraph may jeopardize the validity of the application or this document, or the validity or enforceability of any patent resulting therefrom.

Date: 4/11/05

A handwritten signature in black ink, appearing to read 'Jeff Durkee', written over a horizontal line.

Jeff Durkee

Appendix 1

Babycenter.com consumer comments for the Second Nature nurser

great product

My breastfed baby was having trouble taking a bottle with the Avent nipples. When we switched to these nipples, it was much better!! No milk leaking/spitting from the sides of his mouth, and much less gas - it is remarkably close to breastfeeding! I am very pleased with this product.

Babycenter Shopper

Slow Flow for little ones

I am so glad to find this bottle (nipple). My son had trouble with other brands - they dripped so fast he'd choke & I'd feel horrible. This nipple is just right for him!

Babycenter Shopper

Finally!

I exclusively breastfed the first 4 weeks of my daughter's life as recommended. By the time I was ready to get her used to a bottle so that I could go back to work, the pattern had been set. My daughter refused to take any bottle or nipple I gave her. The milk flowed too fast and she choked on it. Desperate, I finally tried the Second Nature bottle. Thank the heavens! A bottle that didn't choke her and that she would actually drink from! I HIGHLY recommend this bottle!

Christy, newly converted and mother to 7 wk old from Nashville, TN

a must-have for breastfed babies

we tried to give our breast-fed baby a diff bottle (Avent) with a slow-flow nipple at 6 weeks to get her used to expressed breast milk. She choked and was red-faced, and half the milk dribbled down her chin. A big waste of precious milk and, as a result, lots of spitting up. The Second Nature bottle solved all these problems! Baby was able to eat at her own pace and milk didn't flow if she didn't suck - no spilling, no choking, no waste - and she seemed much less confused by the diff between bottle feeding and breast. It's also nice that the nipples are all-stages, no need to buy diff flow nipples as baby gets older. I will only be using these from now on! Highly recommend you give these a try.

KJP, 1st-time mom of an 8-week-old girl from California

Aydin finally takes a bottle.

This bottle is the best bottle on the market, believe me I know I have one of every kind and style. I even have the breast bottle. My son refused the bottle until I got this one. After 4 months of feeding him every hour and half to two hours I can not tell you how much I love this bottle!!!

Toni, a mother of 3 from Hanceville, Alabama

Love this bottle :)

When I returned to work I would pump and send bottles of breast milk to the babysitter. My little girl would let milk run out her mouth and therefor soaked the neck of her clothes every time she tried to take a bottle. I tried a couple of other brands but nothing worked. Until I tried the Second Nature bottle. She doesn't have a bit of trouble taking this bottle and doesn't drip.

Lisa, 1st time mom

Great Bottles!

I have tried just about every different nipple & bottle on the market so my 8 month old breastfeed daughter could drink from a bottle in my absence, we have had no luck until now ... these bottles worked great for us! She took right to the nipple design, drank the full bottle without refusing the nipple or a single fuss!! It is true too ... they really do not leak!! Great product!!!!

Dawn, mother of 2 from Delaware

Saved my breastfeeding

My baby quickly got confused within three days of using a regular nipple and even the smallest conventional nipple was too fast for him. I got the Second Nature and it totally cured the nipple confusion and the choking. I had to teach him how to use the nipple by "teasing him" with my finger. When he started sucking I would switch and put in the SN Nurser and he would continue to suck. As soon as he got milk he continued suckling on his own. I showed my mom how to get him started and she quickly got him drinking regularly. After one day of using the SN exclusively and he had no further problems. And he still breastfeeds beautifully. It takes a little

training, but it's well worth it to preserve breastfeeding.
Gabie, physician and new mom from Las Vegas, NV

Buy these instead of Avent!

I originally bought the Avent bottles for my 3rd child because of the wide mouth design. They were the worst. The formula would run down the sides of my daughter's mouth and the bottles would leak. I tried Second Nature and I admit, at first I was put off by the weird shape of the nipple. But my daughter figured it out right away and what a difference! She is so relaxed when she feeds now because she isn't trying to keep up with the flow of the formula. When she stops sucking, it stops flowing. The harder she sucks, the more she gets. She used to be soaked when she ate, now she doesn't even need a bib! These bottles are wonderful, I encourage everyone to give them a try.

Linda, mom of 3 from Chicago, IL



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DECLARATION OF BILL HUDSON UNDER 37 CFR 1.132

I, the undersigned named inventor, declare as follows.

1. This declaration accompanies a Response to Third Office Action, which is responsive to the Office Action Mailed on 12/14/04.

2. From 1985 until 2002 I held various positions of responsibility within Baby Care Product Development, including the title of Director, at Gerber Products Company ("Gerber") of Parsippany, New Jersey, and in this capacity I was responsible for all product development activities of baby care products at Gerber. This included consumer research, industrial design, engineering, material selection, manufacturing sourcing, and product performance. During this time I was involved in

numerous patent applications and received the Governor's Award for New Products from the State of Wisconsin.

3. Because Gerber is a leading marketer of reusable nursing systems, I spent a great deal of time evaluating nursing systems from around the world and investigating nursing system concepts for development. A standing challenge in this product category is to develop a nipple that functions more like a natural breast nipple. The existing commercial nipples were all designed with cylindrical holes in the feeding surface that were formed by mechanical punching or laser cutting. These did not regulate the flow like a Mother's nipple and would allow continuous liquid flow until the bottle would vacuum lock. The only other nipple design was a cross-cut which provided a method for feeding thicker liquids such as formula that had been blended with cereal.

4. During my tenure at Gerber, we explored various material and feed hole designs in an attempt to replicate the natural nipple. Our goal was to build a nipple that would only allow liquid flow from suction and would consist of multiple openings that would simulate the natural nipple. Despite our best efforts, we were never able to combine the right material with the right design and technology to accomplish this goal. In addition to our internal efforts, I worked with Mapa, the leading nipple manufacturer in Europe, and several manufacturers in Asia on this project. We tried a number of concepts and prototypes without success.

5. As part of my job, I kept abreast of new products from other US companies as well as activities in foreign markets. In spite of specifically looking for a nipple that functioned like

a natural nipple, I never found a product that met this criteria. I know from other product categories, such as no-spill cups and disposable bottles, that we were not alone in looking for this break-through in a nipple design. Yet, like us, there was no evidence that any other company was successful in their effort.

6. I received a Second Nature nipple in December 2004. The Second Nature nipple is the first example I have ever seen that combines the attributes of a nipple that has multiple openings like a natural nipple, has a flow regulated by the amount of suction applied, and doesn't drip. Although my 5 month old daughter is still primarily breast feeding, we occasionally supplement with a bottle. She readily accepted this nipple without hesitation and nursed successfully from it. Based on my observations, the Second Nature nipple simulates the performance of a natural nipple and accomplishes one of the product goals my team spent years trying to create.

7. I declare that all statements made herein of my own respective knowledge are true, all statements made herein on information and belief are believed to be true, and all statements made herein are made with the knowledge that whoever, in any matter within the jurisdiction of the Patent and Trademark Office, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be subject to the penalties including fine or imprisonment or both as set forth under 18 U.S.C. 1001, and that violations of this paragraph may jeopardize the

validity of the application or this document, or the validity or enforceability of any patent resulting therefrom.

Date: April 5, 2005

Bill Hudson

Bill Hudson